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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,092	04/15/2004	T. Douglas Mast	END-5313	7164
27777	7590	11/25/2005	EXAMINER TOY, ALEX B	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,092

Applicant(s)

MAST ET AL.

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 further limits said beam characteristic of claim 2. Claim 2, however, is not limited to positively selecting a beam characteristic as the control parameter. Therefore, claim 3 should read: "... wherein the control parameter is a beam characteristic and wherein the beam characteristic is chosen from ..."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 9-10, 12-15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Freundlich (U.S. Pat. No. 6,618,620 B1).

Regarding claim 1, Freundlich discloses an ultrasound medical treatment system comprising:

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a) an ultrasound medical-treatment transducer 102 (col. 6, ln. 25-30 and Fig. 2);
and

b) a controller 106 which controls the medical-treatment transducer to emit ultrasound to thermally ablate patient tissue (col. 3, ln. 9-13), wherein the control includes a control parameter (col. 7, ln. 30-34), and wherein the controller changes the control parameter based on receiving an indication of an occurrence in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect (col. 9, ln. 24-35 and col. 10, ln. 6-58). Since a rise in tissue temperature depends on the absorption of ultrasound (Martin (U.S. Pat. No. 6,007,499) – col. 2, ln. 56-57) and the amount of ultrasound absorption is related to the amount of attenuation (Burdette (U.S. Pat. No. 5,549,638) – col. 5, ln. 37-60), the controller of Freundlich inherently changes the control parameter based on receiving an indication of an occurrence in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect.

Regarding claim 2, Freundlich discloses the ultrasound medical treatment system of claim 1, wherein the control parameter is chosen from the group consisting of an ultrasonic acoustic power density of the ultrasound emitted by the medical-treatment transducer, an ultrasonic frequency of the ultrasound emitted by the medical-treatment transducer, a beam characteristic of the ultrasound emitted by the medical-treatment transducer, a duty cycle of the ultrasound emitted by the medical-treatment transducer, and a pulse sequence of the ultrasound emitted by the medical-treatment transducer (col. 7, ln. 30-34).

Regarding claim 3, Freundlich discloses the ultrasound medical treatment system of claims 1 and 2, wherein the control parameter is a beam characteristic and wherein the beam characteristic is chosen from the group consisting of an active aperture of the beam, a focusing characteristic of the beam, and a steering angle of the beam (col. 7, ln. 34-38).

Regarding claim 4, Freundlich discloses the ultrasound medical treatment system of claims 1 and 2, wherein the ultrasound-attenuating effect is caused by at least one cause chosen from the group consisting of bubble activity from tissue cavitation, bubble activity from tissue boiling, and a temperature-related change in tissue ultrasonic absorption (col. 9, ln. 24-35 and col. 10, ln. 6-58). In addition, Martin (col. 2, ln. 15-33) and Aida (U.S. Pat. No. 5,485,839 – col. 2, ln. 39-63) disclose that the causes specified in claim 4 are common if not inherent causes of ultrasound attenuation that occur when ablative ultrasound energy is applied to tissue.

Regarding claim 7, see the rejection of claim 4.

Regarding claim 9, Freundlich discloses the ultrasound medical treatment system comprising:

a) an ultrasound medical-treatment transducer 102 (col. 6, ln. 25-30 and Fig. 2);
and

b) a controller 106 which controls the medical-treatment transducer 102 to emit ultrasound at a first ultrasound acoustic power density to thermally ablate patient tissue, wherein the controller reduces the emitted ultrasound to a lower second ultrasound

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acoustic power density based on receiving an indication of an onset in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect (col. 9, ln. 24-35).

Regarding claim 10, Freundlich discloses the ultrasound medical treatment system of claim 9, wherein the lower second ultrasound acoustic power density substantially eliminates the ultrasound-attenuating effect. When the controller 106 of Freundlich lowers the power to lower the tissue temperature in response to sensing an excessively high temperature, the lower second ultrasound acoustic power density inherently substantially eliminates the ultrasound-attenuating effect since the attenuation effect is due to excessively high temperature.

Regarding claim 12, see the rejections of claims 1 and 9.

Regarding claim 13, see the rejections of claims 2 and 12.

Regarding claim 14, see the rejections of claims 3 and 13.

Regarding claim 15, see the rejections of claims 4 and 13.

Regarding claim 18, see the rejections of claims 4 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6, 8, 16-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freundlich ('620) in view of Itoh (U.S. Pat. No. 4,757,820).

Regarding claim 5, Freundlich discloses the ultrasound medical treatment system of claims 1, 2, and 4. In addition, Freundlich discloses an ultrasound system, wherein the indication of the occurrence of the ultrasound-attenuating effect is based on magnetic resonance imaging from the patient tissue (col. 10, ln. 24-58 and Fig. 7B). The claim differs from Freundlich in calling for the imaging to be from ultrasound echoing. Itoh, however, teaches an ultrasound medical treatment system, wherein the imaging is from ultrasound echoing (col. 2, ln. 12-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the imaging system of Freundlich an ultrasound imaging system in view of the teaching of Itoh as an obvious alternate type of imaging system that is well-known in the art. In addition, on page 6, paragraph 22 of the specification, applicant does not disclose any criticality or unexpected result associated with using an ultrasound imaging system.

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Furthermore, applicant specifically discloses that MRI is an acceptable alternate imaging system.

Regarding claim 6, Freundlich discloses the ultrasound medical treatment system of claims 1, 2, and 4. Freundlich further discloses the system of claim 5 in view of Itoh. In addition, Itoh discloses a medical-treatment transducer that is an ultrasound medical-imaging-and-treatment transducer, and wherein the imaging ultrasound echo is received by the medical-imaging-and-treatment transducer (col. 2, ln. 12-24).

Regarding claim 8, see the rejection of claim 5.

Regarding claim 16, see the rejections of claims 5 and 15.

Regarding claim 17, see the rejections of claims 6 and 16.

Regarding claim 19, see the rejections of claims 5 and 12.

Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freundlich ('620) in view of Ying (U.S. Pat. No. 5,657,760).

Regarding claim 11, Freundlich discloses the ultrasound medical treatment system of claims 9 and 10. Ying teaches monitoring tissue treatment using ultrasound imaging, and it would be obvious to use ultrasound imaging in the system of Freundlich – See the rejection of claim 5.

Freundlich discloses adjusting the ultrasound power in response to physiological tissue parameters such as scatter. Scatter changes the tissue absorption of ultrasound

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and causes a rise in tissue temperature that inherently indicates ultrasound attenuation (col. 10, ln. 6-10 and the rejection of claim 1). Thus, detecting scatter by a rise in tissue temperature indicates ultrasound attenuation.

Ying discloses that scatter can be caused by air bubbles (col. 14, ln. 28-44). Furthermore, air bubbles arise during ablation and are hyperechoic. Ying teaches using ultrasound to detect this hyperechogenicity (scatter) to monitor ablation progress (col. 14, ln. 52-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used ultrasound to detect hyperechogenicity instead of temperature in the system of Freundlich in view of the teaching of Ying as an obvious alternate method that is known in the art for monitoring for scatter, an inherent indication of the onset of ultrasound attenuation and a factor affecting ablation progress.

Finally, the site of ultrasound attenuation would inherently be in a region distal to a proximal hyperechoic region because the hyperechoic region of Ying is the site of scatter which leads to the ultrasound attenuation distal from it.

Regarding claim 20, see the rejections of claims 10-12.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 5759154 A
US 4798215 A

USPAT
USPAT

Hoyns; Dirk V.
Turner; Paul F.

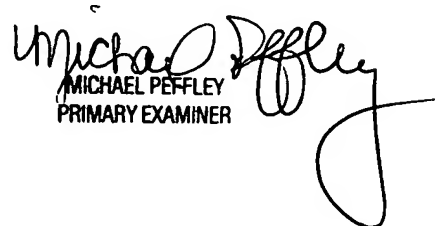
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
11/18/05


MICHAEL PEFFLEY
PRIMARY EXAMINER